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09/600,952	07/25/2000	Edna Chosack	S02/11	4168

7590 04/06/2004

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EXAMINER	
SAADAT, CAMERON	
ART UNIT	**PAPER NUMBER**
3713	15

DATE MAILED: 04/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/600,952	CHOSACK ET AL.	
	Examiner	Art Unit	
	Cameron Saadat	3713	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 12/17/03.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) 28-38 is/are withdrawn from consideration.

5)☒ Claim(s) 18 is/are allowed.

6)☒ Claim(s) 1-17,21-27,39-42,44-52 and 54-56 is/are rejected.

7)☒ Claim(s) 19,20,43 and 53 is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

In response to amendment filed 12/17/03, claims 1-27, 39-45, and newly added claims 46-56 are pending in this application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 46-49 and 54-56 are rejected under 35 U.S.C. 102(b) as being anticipated by Cover "Interactively Deformable Models for Surgery Simulation".

Regarding claim 46, Cover discloses a system for simulating a medical procedure, the system comprising, an instrument for being manipulated for performing the simulated medical procedure; a three-dimensional mathematical model of an organ, such that a virtual location of the instrument in the organ during the simulated medical procedure is determined according to a three-dimensional mathematical model, wherein the model features a spline, said spline determining a geometry of the mathematical model in three dimensions (P. 71, Col 2 – P. 72, Col. 1); a display for providing visual feedback; a tactile feedback mechanism (See P. 74, Col. 2; Fig. 10).

Regarding claim 47, Cover discloses a system wherein deformations in the organ are determined by altering a spline (P. 71, Col 2 – P. 72, Col. 1).

Regarding claim 48, Cover discloses a system wherein local deformations of the organ are determined according to a mathematical model by adding polygons (P. 73 Col. 2 – P. 74, Col. 1).

Regarding claim 49, Cover discloses a system wherein the mathematical model is constructed from a spline by modeling the organ as a straight line and altering the spline until the mathematical model fits the organ (P. 72, Col. 1).

Regarding claim 54, Cover discloses a system for simulating a medical procedure, the system comprising a three-dimensional mathematical model of an organ, wherein the mathematical model is

comprised of a plurality of polygons constructed according to a mathematical spline-based algorithm, the spline determining the geometry of the mathematical model in three dimensions, and the system further provides visual and tactile feedback (P. 71, Col 2 – P. 72, Col. 1; See P. 74, Col. 2; Fig. 10).

Regarding claim 55, Cover discloses a system wherein the algorithms are capable of operating on a standard PC computer processor (P. 73, Col. 2)

Regarding claim 56, Cover discloses a system wherein the algorithms provide real-time visual and haptic feedback (P. 74, Col. 2).

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 54 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The basis of this rejection is set forth as follows:

(1) whether the invention is within the technological arts; and

(2) whether the invention produces a useful, concrete, and tangible result.

Technological Arts Analysis

For a claimed invention to be statutory, the claimed invention must be within the technological arts. Claim 54 includes ideas in the abstract that do not apply, involve, use, or advance the technological arts fail to promote the "progress of science and the useful arts" (i.e., the physical sciences as opposed to social sciences, for example) and therefore are found to be non-statutory subject matter. For claim 54 to pass muster, the recited process must somehow apply, involve, use, or advance the technological arts.

Useful, Concrete and Tangible Analysis

Additionally, for a claimed invention to be statutory, the claimed invention must produce a useful, concrete, and tangible result. See, *State Street Bank and Trust Co. v. Signature Financial Group Inc.*, 149 F.3d at 1373, 47 USPQ2d at 1601-02 (Fed. Cir. 1998). A process that consists solely of the

manipulation of an abstract idea is not concrete or tangible. See *In re Warmerdam*, 33 F.3d 1354, 1360, 31 USPQ2d 1754, 1759 (Fed Cir. 1994).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10, 40-42, 44-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobus et al. (U.S. Patent No. 5,769,640; hereinafter Jacobus) in view of Cover "Interactively Deformable Models for Surgery Simulation".

Regarding claim 1, 44-45 Jacobus discloses a system for performing a simulated medical procedure comprising: a simulated organ (column 7, lines 4-9; column 10, line 27), a simulated instrument 134 (column 7, lines 55-56); a locator 46 for determining a location of the simulated instrument within the simulated organ; a visual display for displaying images according to location of a simulated instrument within the simulated organ (column 5, lines 20-22), such that the images simulate actual visual data received during an actual medical procedure as performed on an actual subject (Column 4, lines 31-38), the visual display including a mathematical model 124 for modeling the simulated organ according to a corresponding actual organ; said model is divided into a plurality of segments and the display further includes a loader for selecting at least one of said plurality of segments for display based on the position

of the simulated instrument 134 (column 7, lines 5-9), and displayer 56 for displaying the simulated image. Jacobus further discloses: a three-dimensional graphics generator 52 for generation of three-dimensional images of simulated *instrument* 134 (column 5, lines 28-31), but is not explicitly disclosed that the mathematical model of the *organ* is three-dimensional. However, Cover teaches a system for performing a simulated medical procedure comprising a three-dimensional mathematical model for modeling a simulated organ. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the mathematical model of the simulated instrument described by Jacobus, by providing a three-dimensional mathematical model of an organ as well, in order to provide a more realistic surgery simulation.

In addition, Jacobus does not explicitly disclose that the plurality of *segments are arranged in a linear sequence* (as per claims 1, 44-45). Although not explicitly stated, this feature is implicit, since both Jacobus and Cover disclose a medical simulation of an endoscope being inserted into an aperture that represents an organ. It is implicit that the motion of said insertion requires a linear motion, and therefore the simulator loads stored image data that is arranged and loaded on a display based on the discrete position data of the instrument that is maneuvered in a linear motion. (Jacobus, column 5, lines 20-22; Cover P. 74, col. 2).

Jacobus discloses all of the claimed subject matter of claim 44 with the exception of explicitly disclosing the feature of *texture mapping.* However, Cover teaches a system for performing a simulated medical procedure comprising a three-dimensional mathematical model of a simulated organ wherein texture-mapping data is added to the simulated organ (Cover, P. 74, Col.2, ¶4). Hence, in view of Cover, it would have been obvious to an artisan to modify the simulated organ described in Jacobus, by providing the simulated organ with texture-mapping data in order to greatly enhance the realism of the simulator (See Cover P. 74, Col.2, ¶4)

Regarding claims 2-4, Jacobus discloses a visual displayer 56, image database 42 and graphics overlay engine 54 (as per claim 2); a database 42 comprising animation of random movements of simulated instrument and random movement of simulated organ (as per claim 3), wherein the data includes images obtained from performing an actual medical procedure on an actual subject (as per claim

4) (see column 4, lines 39-49). Jacobus discloses all of the claimed subject matter of claims 2-4 with the exception of explicitly disclosing the feature of *texture mapping.* However, Cover teaches a system for performing a simulated medical procedure comprising a three-dimensional mathematical model of a simulated organ wherein texture-mapping data is added to the simulated organ (Cover, P. 74, Col.2, ¶4). Hence, in view of Cover, it would have been obvious to an artisan to modify the simulated organ described in Jacobus, by providing the simulated organ with texture-mapping data in order to greatly enhance the realism of the simulator (See Cover P. 74, Col.2, ¶4)

. Regarding claim 5, Jacobus discloses a system in which the images are obtained by recording visual data during a medical procedure and selecting said images from the recorded visual data (See Fig. 5).

Regarding claims 6-9, 40 and 45 Jacobus discloses a mathematical model of an organ wherein images of the organ are morphed through corresponding polygon patches for creating interpolated images. Jacobus does not explicitly disclose a mathematical model of an organ constructed *according to a spline* (as per claims 6 and 40), wherein deformations in the simulated organ are determined by altering the spline (as per claims 7-8). However, Cover discloses a system for simulating a medical procedure comprising a mathematical model of an organ, wherein the model and deformations to the model are determined by a spline. In view of Cover, it would have been obvious to one of ordinary skill in the art to provide a simulated organ based on a *spline* in order to extract features from 2D images to provide a model comprising interactively deformable surfaces in 3D space, thereby providing a model wherein the mathematical representation provides a framework for creating 3D images having meaningful properties of elasticity and flexibility and thereby enhancing simulation of an instrument interacting with an organ, wherein the contour of the organ can be manipulated by applying forces (See Cover, P. 71, col. 2 – P. 72, Col. 1).

Regarding claim 10, the combination of Jacobus discloses a medical simulator including image selection according to one previous movement of a simulated instrument within a simulated organ. (column 5, lines 20-28).

Regarding claims 41-42, Jacobus discloses a simulated endoscopic procedure, however does not explicitly disclose an endoscope that comprises a tool unit. Cover teaches a medical simulator for performing procedures with laparoscopy tools wherein the tools are simulated to grab and cut tissue. Furthermore, Gillio teaches a simulated endoscope comprising a tool unit further comprising simulated forceps, and a channel within the handle for receiving the simulated forceps; a tool control unit in communication with a computer for detecting movement of the simulated forceps and providing visual (as per claim 24) and tactile feedback (column 14, line 66 – column 15, line 34). Hence, the combination of references clearly suggests simulation of a stereotactic tool for simulating stereotactic procedures requiring cutting and grabbing, yet do not expressly disclose a simulated loop for performing a polypectomy. However, it is the examiner's position that stereotactic tools are notoriously known for having loops to carry out a polypectomy procedure, wherein the loop is presented on a display (See Nowinski et al. Fig. 23a). Hence, it would have been obvious to a person of ordinary skill in the art to modify the simulation described in the combination of Jacobus and Cover, by providing a simulated endoscope comprising a *loop* in order to simulate the feature of cutting tissue with a loop, formed by a wire, during a stereotactic procedure.

Claims 11-17, 21, 23-27, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobus et al. (U.S. Patent No. 5,769,640; hereinafter Jacobus) in view of Cover "Interactively Deformable Models for Surgery Simulation", further in view of Gillio (U.S. Patent No. 5,882,206).

Regarding claims 11-12, combination of Jacobus and Cover discloses the use of a display, but does not explicitly teach the use of a graphical user interface (as per claim 11) and does not expressly teach a graphical user interface that displays tutorial information (as per claim 12). However, Gillio teaches a medical simulator comprising a graphical user interface (column 5, lines 27-31), and also a graphical user interface that displays tutorial information (column 3, lines 8-11). In view of Gillio, it would have been obvious to one of ordinary skill in the art to modify the simulator described the combination of Jacobus and Cover, by providing a graphical user interface and tutorial information, thereby allowing a student to easily interact with the simulator and receive helpful information regarding a medical procedure.

Regarding claims 13-14, Jacobus discloses a simulated organ (column 10, line 27) but does not specify the organ as being a gastro-intestinal tract (as per claim 13). However, Jacobus discloses that the simulated medical procedure comprises an endoscopic procedure, and that the simulated model of the organ comprises data representing semi-flexible and smooth characteristics (column 10, lines 45-49). Furthermore, Cover discloses a system that simulates an inner lumen of the stomach, and small intestines, or colon, in order to simulate laparoscopic procedures of intra-abdominal organs. It is not explicitly stated that the simulated organ is constructed of semi-flexible *material* (as per claim 14). However, Gillio teaches a simulated organ as being a *gastro-intestinal tract* (column 7, lines 39-43). Furthermore, Gillio teaches a simulated organ 110 comprising virtual orifice 112, and wherein the surface of the orifice is adjusted (column 7, lines 29-31; column 6, lines 64-66) with springs and rollers pressing against the orifice wall, and thereby teaches semi-flexible material characteristics. In view of Gillio, it would have been obvious to a person of ordinary skill in the art to modify the simulated organ described in the combination of Jacobus and Cover, by providing a simulated organ of a gastro-intestinal tract comprising an orifice wall comprising *material* having smooth, semi-flexible material, in order to accurately represent physical characteristics of an organ and thereby enhance realism of a simulated endoscopic procedure.

Regarding claim 15, Jacobus discloses a simulated instrument 48 comprising a sensor for determining the location of the simulated instrument within the simulated organ, and a computer 44 to provide visual feedback of the simulated instrument location (column 5, lines 11-19).

Regarding claim 16, Jacobus discloses a tactile feedback mechanism 46/48 corresponding to the location of the simulated instrument within a simulated organ. Although Jacobus does not expressly disclose that the location sensor is positioned at the tip of the endoscope (as per claim 16), it is the examiner's position that positioning a location sensor at the tip of an endoscope is old and well known. Hence, it would have been obvious to a person of ordinary skill in the art to modify the position of the location sensor of the endoscope described in Jacobus, and positioning it on the tip of the endoscope because it is critical for a trainee or surgeon to be aware of the location of the tip of the endoscope with respect to a patient's organ, to prevent damage, and to guide the instrument within the organ.

Regarding claim 17, Jacobus discloses a force reflective mechanism 140 that provides tactical feedback on the simulated instrument with servo-motors, but does not specifically teach that the mechanism is contained in a gastro-intestinal tract. However, Gillio teaches a tactile feedback mechanism located in the gastro-intestinal tract comprising servo-motors, wherein the rollers 230, 232, 234, and 236 can be fitted with the servo-motors to contact the semi-flexible material of the orifice 112 of the simulated organ 110; a controller for controlling the servo-motors, such that the position of the rollers is determined by the controller in order to provide tactile feedback (column 7, lines 12-20). Although a piston is not specified, it is the examiner's position that it would have been an obvious matter of choice well within the capabilities of one skilled in the art to use a piston in place of the rollers described by Gillio because this feature provides no criticality with respect to the invention. Thus, it would have been obvious to a person of ordinary skill in the art to modify the simulated organ tactile feedback mechanism described in the combination of Jacobus and Cover, by providing tactile feedback *contained in a gastro-intestinal track* in order to provide a simulated organ with an adjustable orifice to simulate various types of organs (see Gillio, column 7, lines 29-36).

Regarding claim 21, Jacobus et al. discloses a simulated organ tract that is substantially a straight tube, such that the tactile feedback and visual feedback are substantially independent of a geometrical shape of the simulated organ tract (see Fig. 9, ref. 136).

Regarding claim 23-24, Jacobus discloses a simulated endoscopic procedure, however does not explicitly disclose an endoscope that comprises a tool unit. Cover teaches a medical simulator for performing procedures with laparoscopy tools wherein the tools are simulated to grab and cut tissue. Furthermore, Gillio teaches a simulated endoscope comprising a tool unit further comprising simulated forceps, and a channel within the handle for receiving the simulated forceps; a tool control unit in communication with a computer for detecting movement of the simulated forceps and providing visual (as per claim 24) and tactile feedback (column 14, line 66 – column 15, line 34). Thus, it would have been obvious to a person of ordinary skill in the art to modify the endoscopic simulation described in the combination of Jacobus and Cover, by providing a simulated endoscope comprising a *tool unit* in order to simulate the feature of grabbing tissue during an endoscopic procedure.

Regarding claim 25, the combination of Jacobus, Cover, and Gillio discloses a simulated endoscopic instrument comprising a control unit detects the motion of simulated forceps (Gillio, column 20, lines 60-65), but does not specify a detection of a roll for displaying visual feedback (as per claim 25). However, it would have been obvious to an artisan to provide visual feedback of not only in/out movements, but also roll movements that are associated with endoscopic procedures in order to provide a realistic simulation of an actual endoscopic medical procedure.

Regarding to claim 39, Jacobus et al. discloses that a loader stores segments of the organ model in real-time (column 4, lines 10-13). The examiner takes official notice that the use of RAM is old and well known.

Regarding claim 26, Jacobus discloses a simulated endoscopic procedure, however does not explicitly disclose an endoscope that comprises a tool unit. Cover teaches a medical simulator for performing procedures with laparoscopy tools wherein the tools are simulated to grab and cut tissue. Furthermore, Gillio teaches a simulated endoscope comprising a tool unit further comprising simulated forceps, and a channel within the handle for receiving the simulated forceps; a tool control unit in communication with a computer for detecting movement of the simulated forceps and providing visual (as per claim 24) and tactile feedback (column 14, line 66 – column 15, line 34). Hence, the combination of references clearly suggests simulation of a stereotactic tool for simulating stereotactic procedures requiring cutting and grabbing, yet does not expressly disclose a simulated loop for performing a polypectomy. However, it is the examiner's position that stereotactic tools are notoriously known for having loops to carry out a polypectomy procedure, wherein the loop is presented on a display (See Nowinski et al. Fig. 23a). Hence, it would have been obvious to a person of ordinary skill in the art to modify the simulation described in the combination of Jacobus, Cover, and Gillio, by providing a simulated endoscope comprising a *loop* in order to simulate the feature of cutting tissue with a loop, formed by a wire, during a stereotactic procedure.

Regarding claim 27, Jacobus discloses a system for performing a simulated medical procedure comprising: a simulated organ (column 7, lines 4-9; column 10, line 27), a simulated instrument 134 (column 7, lines 55-56); a locator 46 for determining a location of the simulated instrument within the

simulated organ; a visual display for displaying images according to location of a simulated instrument within the simulated organ (column 5, lines 20-22), such that the images simulate actual visual data received during an actual medical procedure as performed on an actual subject (Column 4, lines 31-38), the visual display including a mathematical model 124 for modeling the simulated organ according to a corresponding actual organ; said model is divided into a plurality of segments and the display further includes a loader for selecting at least one of said plurality of segments for display based on the position of the simulated instrument 134 (column 7, lines 5-9), and displayer 56 for displaying the simulated image. Jacobus further discloses: a three-dimensional graphics generator 52 for generation of three-dimensional images of simulated *instrument* 134 (column 5, lines 28-31), but is not explicitly disclosed that the mathematical model of the *organ* is three-dimensional. However, Cover teaches a system for performing a simulated medical procedure comprising a three-dimensional mathematical model for modeling a simulated organ. At the time of the invention, it would have been obvious to a person of ordinary skill in the art to modify the mathematical model of the simulated instrument described by Jacobus, by providing a three-dimensional mathematical model of an organ as well, in order to provide a more realistic surgery simulation.

In addition, Jacobus does not explicitly disclose that the plurality of *segments are arranged in a linear sequence*. Although not explicitly stated, this feature is implicit, since both Jacobus and Cover disclose a medical simulation of an endoscope being inserted into an aperture that represents an organ. It is implicit that the motion of said insertion requires a linear motion, and therefore the simulator loads stored image data that is arranged and loaded on a display based on the discrete position data of the instrument that is maneuvered in a linear motion. (Jacobus, column 5, lines 20-22; Cover P. 74, col. 2)

Jacobus further discloses a simulated endoscopic procedure, however does not explicitly disclose an endoscope that comprises a tool unit. Cover teaches a medical simulator for performing procedures with laparoscopy tools wherein the tools are simulated to grab and cut tissue. Furthermore, Gillio teaches a simulated endoscope comprising a tool unit further comprising simulated forceps, and a channel within the handle for receiving the simulated forceps; a tool control unit in communication with a computer for detecting movement of the simulated forceps and providing visual (as per claim 24) and

tactile feedback (column 14, line 66 – column 15, line 34). Thus, it would have been obvious to a person of ordinary skill in the art to modify the endoscopic simulation described in the combination of Jacobus and Cover, by providing a simulated endoscope comprising a *tool unit* in order to simulate the feature of grabbing tissue during an endoscopic procedure.

Claims 50-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cover "Interactively Deformable Models for Surgery Simulation", in view of Gillio (U.S. Patent No. 5,882,206), further in view of Nowinski et al. (USPN 6,701,173; hereinafter Nowinski).

Regarding claims 50-52, Cover teaches a medical simulator for performing procedures with laparoscopy tools wherein the tools are simulated to grab and cut tissue (P. 74, Col. 2). Cover does not explicitly disclose forceps. However, Gillio teaches a simulated endoscope comprising a tool unit further comprising simulated forceps, and a channel within the handle for receiving the simulated forceps; a tool control unit in communication with a computer for detecting movement of the simulated forceps and providing visual (as per claim 24) and tactile feedback (column 14, line 66 – column 15, line 34). Thus, it would have been obvious to a person of ordinary skill in the art to modify the endoscopic simulation described in the combination of Jacobus and Cover, by providing a simulated endoscope comprising a *tool unit* in order to simulate the feature of grabbing tissue during an endoscopic procedure. Hence, the combination of Cover and Gillio clearly suggests simulation of a stereotactic tool for simulating stereotactic procedures requiring cutting and grabbing, yet does not expressly disclose a simulated loop for performing a polypectomy. However, Nowinski discloses a stereotactic tool comprising a loop for cutting tissue (See Nowinski et al. Fig. 23a). Hence, in view of Nowinski, it would have been obvious to a person of ordinary skill in the art to modify the simulation described in the combination of Cover and Gillio, by providing a simulated endoscope comprising a *loop* in order to simulate the feature of cutting tissue with a loop, formed by a wire, during a stereoscopic procedure.

Allowable Subject Matter

Claim 18 is allowed.

Claims 19-20, 43, and 53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is an examiner's statement of reasons for allowance: Patentability is seen in, although not limited to:

- Independent claim 18, elements specifically claimed including a guiding sleeve connected to the tip on an endoscope comprising a ball bearing for rolling along an inner surface of a gastro-intestinal tract; and wherein a linear motor is attached to the guiding sleeve for providing tactile feedback by contacting the inner surface of the gastrointestinal tract.
- Dependent claim 19, elements specifically claimed including, a tactile feedback mechanism comprising a plurality of inflatable rings surrounding an endoscope.
- Dependent claims 43 and 53, a system for simulating a medical procedure comprising a simulated organ and a simulated instrument, wherein the simulated instrument is an endoscope featuring an endoscope cable, the endoscope cable forming a loop that is modeled according to a mathematical model, wherein the mathematical model features a plurality of polygons defined with respect to a spline, and wherein a size of the loop is determined according to a differential between an amount of the cable within the organ and a length of the organ from an entry point of the endoscope to the virtual location of the endoscope within the organ.

Response to Arguments

Applicant's arguments with respect to claims 1-27, 39-56 have been considered but are moot in view of the new ground(s) of rejection. It has been determined that Matsuzaki (US 5,882,206) is not applicable as prior art. Therefore, the rejection based on Matsuzaki mailed 7/17/03 has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cameron Saadat whose telephone number is 703-305-5490. The examiner can normally be reached on M-F 8:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Teresa J Walberg can be reached on 703-308-1327. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

CS

T. Walberg
Teresa Walberg
Supervisory Patent Examiner
Group 3700